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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/673,046

09/26/2003

David M. Gravett

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

09/19/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/673,046

Applicant(s)

GRAVETT ET AL.

Examiner

Blessing M. Fubara

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-231 is/are pending in the application.
- 4a) Of the above claim(s) 5-7, 15, 18-25, 28-33, 42-66, 70, 71 and 73-231 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8-14, 16, 17, 26, 27, 34-41, 67-69 and 72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/19/06.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

The Office Action of 4/11/07 is vacated in order to examine claims 34-41 with claims 1-4, 8-14, 16, 17, 26, 27, 67-69 and 72.

Examiner acknowledges receipt of IDS filed 12/19/06. The examiner further acknowledges receipt of the response to the election/restriction requirement of 10/26/06.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-93, in the reply filed on 10/26/06 is acknowledged. The traversal is on the ground(s) that requiring election of species based on the BAB or ABA or alginate or chitosan or polyurethane or hyaluronic acid or polyhydroxyethylmethacrylate is improper because claim 17 is generic to the species found in claims 20-54. This is not found persuasive because claim 20 is a film, claim 21 is a wrap, claim 22 is a gel, claim 23 is a foam, claim 24 is a mold and claim 25 is a coating. The search for these different species in separate claims is a burden on the search and consideration process. Applicant elected single layer mesh (claim 9), wrap (claim 21), poly(D,L-lactide) as the polyester polymeric carrier (claims 17, 34, 35, 37), paclitaxel as the anti-angiogenic agent (claims 67, 69). However, applicant identified claims 1-4, 8-14, 16, 17, 21, 26, 27, 34-37, 65-69 and 72 as the claims that read on the elected species. However, Claims 65 and 66 are a device having a weft and a warp and applicant has elected a mesh wrap. Since claim 21 is a wrap and wrap is not elected, claim 21 is not examined. Therefore, claims 1-4, 8-14, 16, 17, 26, 27, 34-41, 67-69 and 72 are examined.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4, 8, 9, 14, 16, 17, 26, 27, 34-37, 67-69 and 72 are rejected under 35

U.S.C. 102(b) as being anticipated by Hunter et al. (US 5,716,981).

Hunter discloses an anti-angiogenic composition in the form of a mesh (column 22, lines 51 and 52; column 26, lines 24-26), the mesh comprises anti-angiogenic compound and biodegradable carrier compound (column 3, lines 44-61), which is polyester, polymers and oligomers and copolymers of lactides and glycolides, such a polylactide, polyglycolides and lactide-glycolides or PLGA and blends thereof (column 16, lines 31-56). Example 28 uses paclitaxel as the therapeutic agents such as paclitaxel (Example 28). The device of claim 1 reads on the composition of Hunter. Regarding claim 2, Hunter does not have a backing or does not indicate woven and as such the mesh comprising the carrier and anti-angiogenic agent meets claim 2. Example 28 also uses either PCL or PDLLA or PLGA and uses 50:50 PLGA (column 78, lines 21, 55). The paclitaxel of Hunter meets claims 67-69. The composition of Hunter having the therapeutic agent, anti-angiogenic agent or paclitaxel and polymer carrier, such as PLGA, MePEG-PLGA (column 18, line 35) meets the limitations of claims 26 and 34-37. Claim 72 recites the intended use or properties of the composition claim 1 and the composition of Hunter inherently possesses these properties and is also capable of performing the intended use.

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3. Claims 1, 3, 4, 8, 9, 14, 16, 17, 26, 34-37 and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by Yang et al. ("Physicochemical aspects of drug delivery and release from polymer-based colloids," in *Current Opinion in Colloid & Interface Science, Volume 5, Issues 1-2, March 2000, Pages 132-143*).

Yang describes a drug delivery device that comprises biodegradable polymer such poly(lactide-co-glycolide) matrices and the polymer is in the form of mesh, the device comprises paclitaxel as an active agent (paragraphs 4 and 5) and poly(lactide-co-glycolide) as carrier material such that the teachings of Yang anticipate the designated claims. Claim 72 recites the intended use or properties of the composition claim 1 and the composition of Yang inherently possesses these properties and is also capable of performing the intended use. Regarding claim 2, Yang does not have a backing or does not indicate woven and as such the mesh comprising the carrier and therapeutic agent meets claim 2.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 10-13 and 38-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter et al. (US 5,716,981) in view of Chern et al. (US 6,733,767) or Yang et al.

("Physicochemical aspects of drug delivery and release from polymer-based colloids," in *Current Opinion in Colloid & Interface Science, Volume 5, Issues 1-2, March 2000, Pages 132-143*) in view of in view of Chern et al. (US 6,733,767).

A) Hunter in view of in view of Chern et al. (US 6,733,767):

Hunter is described above as anticipating claims 1-4, 8, 9, 14, 16, 17, 26, 27, 34-37, 67-69 and 72. Hunter does not specifically disclose the ratio of the lactide to glycolide in the PLGA copolymer. However, it is known in the art that PLGA having ratios of from 75:25 to about 65:35 are used in the delivery of hydrophobic bioactive agent (see Chern at claim 4, 6, 8 and 10). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use PLGA having ratios of lactide to glycolide that would be expected to produce the desired solubility and delivery of the hydrophobic drug of interest.

B) Yang in view of in view of Chern et al. (US 6,733,767):

Yang is described above as anticipated claims 1, 3, 4, 8, 9, 14, 16, 17, 26, 34-37 and 72. Yang does not specifically disclose the ratio of the lactide to glycolide in the PLGA copolymer. However, it is known in the art that PLGA having ratios of from 75:25 to about 65:35 are used in the delivery of hydrophobic bioactive agent (see Chern at claim 4, 6, 8 and 10). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to

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use PLGA having ratios of lactide to glycolide that would be expected to produce the desired solubility and delivery of the hydrophobic drug of interest.

Claim Objections

7. Claim 13 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, amendment to claim 13 to comply with MPEP § 608.01(n) is required.

8. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification including the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Blessing Fubara
Patent Examiner
Tech. Center 1600

A handwritten signature in black ink, appearing to read "Blessing Fubara", is written over the printed name.